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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,294	04/03/2001	Jiangchun Xu	210121.484C5	4060

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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/14/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,294

Applicant(s)

XU ET AL.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-18 is/are pending in the application.
- 4a) Of the above claim(s) 2,5-7,9,10 and 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,11 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants' arguments, filed 27 February 2003, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1, 3, 4, 11, and 15 are currently pending. Applicant is requested to please cancel claims to non-elected inventions.

Information Disclosure Statement

The IDS, filed 27 February 2003 has been entered and considered. An initialed copy of the form PTO-1449 is included with this office action.

Claim Objections

Claim 15 is objected to for being dependent from a cancelled claim. Claim 15 is dependent from claim 8, now cancelled and incorporated into claim 1. Claim 15 will be examined as being dependent from claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1, 3, 4, 11, and 15 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The enablement rejection from the previous Office Action is maintained in all aspects. Applicants submit that the present application is directed to sequences that are expressed in ovarian tumor tissue versus normal tissue and that the sequences may be used for the detection of ovarian cancer. Further Applicants state that the instant specification is replete with guidance on tumor specificity of the Applicant's polynucleotides in the detection of ovarian cancer. To provide support for these statements, Applicant has pointed to page 105, lines 8-11, which describe clone 57887, which is SEQ ID NO:199.

This support is not persuasive in that SEQ ID NO:199 is **not** SEQ ID NO:214. As stated in the previous Office Action, SEQ ID NO: 214 is described on page 107 as the "consensus sequence for 0134C/0591S". The significance of this information is not disclosed. The consensus sequence from homologous sequences may not represent a real sequence, as there are many alternative sequences that could represent the consensus, as well as many mistakes that can occur in the generation of a consensus sequence. For instance, there may be a mistake in one or more of the nucleotides of one or both fragments which would lead to the generation of an incorrect sequence. In that case, the sequence may not be expressed, as alteration in even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances. There is nothing in the specification that shows that SEQ ID NO:214 has actually been tested for the biological activity or whether this also is an asserted biological activity based upon sequence similarity to yet a different sequence. As such, there is nothing in the specification that identifies "how" the consensus sequence was generated that would lead one to the conclusion that because SEQ ID NO:210 and SEQ ID NO:199 are expressed in ovarian tumors, so is SEQ ID NO:214.

Applicant has not provided a prima facie case to overcome the argument that "tumor" markers in the art have been shown to be present in non-tumor tissues such that one of skill in the art would have an expectation that any one sequence would be indicative of cancer. "To overcome a prima facie case of lack of enablement, applicant must demonstrate by argument and/or evidence that the disclosure, as filed, would have enabled the claimed invention for one skilled in the art at the time of filing" (MPEP 2164.04). Applicant has not shown that SEQ ID NO:214 is specific for any cell type, let alone ovarian tissue or that it is diagnostic of any cancer and this would be undue experimentation beyond the disclosed embodiments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 11, and 15 remain rejected under 35 U.S.C. 102(b) as being anticipated by McKee et al. (Genomics (1997) vol.46, no.3, pages 426-434).

Applicant has argued that the cancellation of claim 8 and the addition of "highly stringent" conditions instead of "moderately stringent" conditions are sufficient to overcome the prior art rejection. However, this sequence contains at least 20 contiguous residues of SEQ ID.

No:214.

↓ inherently if genomic teaches other strand. but if McKee is cDNA then no.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

if they only teach cDNA

if they teach "genomic" then still stands.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

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May 7, 2003

Lori A. Clow, Ph.D.
Art Unit 1631

Lori A. Clow

mw
MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600